

Manufacturer:	Sterisets International B.V. Ketelmeer 3 – 5347 JX Oss, The Netherlands Tel: +31 412 667 755 Email info@sterisets.com www.sterisets.com
Medical devices:	
Designation:	Intended purpose:
Surgical drapes Wrapping fields Bibs Drapes Drawsheets	For draping of patients and wrapping of medical devices to prevent transfer of infective agents
Risk Class:	According to Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. Class I
Rule:	1
Conformity assessment route:	Annex IX
ISO 9001 certificate no. :	2156451
Certification company:	DEKRA Certification B.V.

We hereby declare that the above mentioned medical devices meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. This EU Declaration of Conformity is issued under sole responsibility of Sterisets International B.V. and according to Annex IV of the referred Regulation. This DoC is valid for the products mentioned on the addendum.

Signature:

Name: Jos van der Kwartel

Function: Management representative

Place and Date:

To DoC number: DoC2156451-4 The medical devices which fall under the DoC are:

Product category: **Surgical drapes, Wrapping fields, Bibs, Drapes, Drawsheets**

REF	Designation	Basic UDI-DI	Trade name
1001	Wrapping field PE/Tissue 38 x 41 cm green	872059888WRAPFIELF314X	medisp
1002	Wrapping field PE/Tissue 38 x 43 cm blue	872059888WRAPFIELF314X	medisp
1003	Wrapping field PE/Tissue 50 x 50 cm green	872059888WRAPFIELF314X	medisp
1004	Wrapping field PE/Tissue 50 x 70 cm blue	872059888WRAPFIELF314X	medisp
1006	Wrapping field PE/Tissue 70 x 50 cm green	872059888WRAPFIELF314X	medisp
1007	Wrapping field PE/Tissue 50 x 70 cm blue	872059888WRAPFIELF314X	medisp
1009	Wrapping field PE/Tissue 70 x 60 cm green	872059888WRAPFIELF314X	medisp
1010	Wrapping field PE/Tissue 70 x 60 cm green	872059888WRAPFIELF314X	medisp
1013	Wrapping field PE/Tissue 70 x 90 cm green	872059888WRAPFIELF314X	medisp
1014	Doek 2 laags PE tissue niet gevouwen	872059888WRAPFIELF314X	medisp
1015	Wrapping field PE/Tissue 70 x 90 cm blue	872059888WRAPFIELF314X	medisp
1052	Drawsheets 210 x 80 cm transparent	872059888DRAWSHEEF9YR	medisp
1054	Drawsheet 210 x 80 cm with 50 threads	872059888DRAWSHEEF9YR	medisp
1073	Draglakan 140 x 80 cm, 44gr/m2	872059888DRAWSHEEF9YR	medisp
1078	Draglakan 150 x 80 cm 44 g / m2	872059888DRAWSHEEF9YR	medisp
1080	Drawsheets 170 x 80 cm, 47g / m2	872059888DRAWSHEEF9YR	medisp
1082	Drawsheet 170 x 80 cm with 50 threads	872059888DRAWSHEEF9YR	medisp
1087	Drawsheet 190 x 80 cm with 50 threads	872059888DRAWSHEEF9YR	medisp
1091	Bib dental 38 x 30 cm	872059888BIBSSSSF33UA	medisp
1100	Drape PE/Tissue 38 x 43 cm blue	872059888DRAPESSSF8YB	medisp
1101	Drape PE/Tissue 38 x 43 cm green	872059888DRAPESSSF8YB	medisp
1102	Drape 2 ply 38 x 46 cm, PE tissue folded	872059888DRAPESSSF8YB	medisp
1103	Drape PE/Tissue 38 x 43 cm green	872059888DRAPESSSF8YB	medisp
1104	Drape 2 ply 55 x 60 cm, PE tissue folded	872059888DRAPESSSF8YB	medisp
1105	Drape 2 ply 50 x 50 cm green	872059888DRAPESSSF8YB	medisp
1107	Drape PE/Tissue 50 x 60 cm green	872059888DRAPESSSF8YB	medisp
1111	Drape PE/Tissue 50 x 80 cm outside folded green	872059888DRAPESSSF8YB	medisp
1112	Drape PE/Tissue 70 x 50 cm green	872059888DRAPESSSF8YB	medisp
1113	Drape PE/Tissue 70 x 90 cm green	872059888DRAPESSSF8YB	medisp
1115	Drape 2 ply 70 x 90 cm, PE tissue folded	872059888DRAPESSSF8YB	medisp
1120	Drape PE/Tissue 45 x 75 cm green	872059888DRAPESSSF8YB	medisp
1140	Drape 2 ply 55 x 60 cm, PE tissue, hole ø 5 cm, slit, folded	872059888DRAPESSSF8YB	medisp
1141	Drape PE/Tissue 50 x 50 cm with fen. Ø 9 cm green	872059888DRAPESSSF8YB	medisp
1144	Drape PE/Tissue 50 x 80 cm with fen. Ø 10 cm green	872059888DRAPESSSF8YB	medisp
1145	Drape PE/Tissue 50 x 80 cm with fen. Ø 6 cm & split green	872059888DRAPESSSF8YB	medisp
1146	Drape PE/Tissue 50 x 80 cm with fen. Ø 6 cm green	872059888DRAPESSSF8YB	medisp
1147	Drape PE/Tissue 50x80cm w. fen. diamond Ø8,5cm & split green	872059888DRAPESSSF8YB	medisp
1148	Drape PE/Tissue 50 x 50 cm with fen. Ø 6 cm green	872059888DRAPESSSF8YB	medisp
1149	Drape PE/Tissue 50 x 80 cm with split green	872059888DRAPESSSF8YB	medisp

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Product category: **Surgical drapes, Wrapping fields, Bibs, Drapes, Drawsheets**

REF	Designation	Basic UDI-DI	Trade name
1150	Drape PE/Tissue 55 x 60 cm with fen. Ø 6 cm + 4 adh. corners	872059888DRAPESSF8YB	medisp
1151	Drape PE/Tissue 70 x 90 cm with fen. Ø 6 cm green	872059888DRAPESSF8YB	medisp
2451	Jaw drape 3 ply 90 x 150 cm, T/PE/NW folded	872059888DRAPESSF8YB	medisp
3201	Wrapping field 2 ply PE 33 gr/m2 NW 30 gr/m2 50 x 70 cm blue	872059888WRAPFIELF314X	medisp
3202	Wrapping field 2 ply PE 33 gr/m2 NW 30gr/m2 75 x 75 cm blue	872059888WRAPFIELF314X	medisp
3203	Wrapping field 2 ply PE 33 gr/m2 NW 30 gr/m2 75 x 90 cm blue	872059888WRAPFIELF314X	medisp
3204	Wrapping field 2 ply PE 33 gr/m2 NW 30 gr/m2 90 x 90 cm blue	872059888WRAPFIELF314X	medisp
3205	Drape 2 ply 75 x 110 cm, 60 g/m2 PE/NW not folded	872059888DRAPESSF8YB	medisp
3206	Drape 2 ply 100 x 100 cm, 60 g/m2 PE/NW not folded	872059888DRAPESSF8YB	medisp
3207	Wrapping field 2 ply PE 33gr/m2 NW 30 gr/m2 90 x 150 cm blue	872059888WRAPFIELF314X	medisp
3210	Drape 2 ply PE 33 gr/m2 NW 30 gr/m2 40x60cm	872059888DRAPESSF8YB	medisp
3211	Drape 2 ply 70 x 50 cm, 60 g/m2 PE/NW folded	872059888DRAPESSF8YB	medisp
3213	Drape 2 ply 70 x 90 cm, 60 g/m2 PE/NW folded	872059888DRAPESSF8YB	medisp
3214	Drape 3 ply 90 x 90 cm, 54 g/m2 T/PE/NW folded	872059888DRAPESSF8YB	medisp
3215	Drape 2 ply PE 33 gr/m2 NW 30 gr/m2 40x45 cm	872059888DRAPESSF8YB	medisp
3217	Drape 2 ply 90 x 150 cm, 60 g/m2 PE/NW folded	872059888DRAPESSF8YB	medisp
3223	Drape 3 ply 60 x 60 cm, 54 g/m2 T/PE/NW folded, with adhesive	872059888DRAPESSF8YB	medisp
3224	Drape 2 ply 70 x 90 cm, PE/NW folded, with adhesive	872059888DRAPESSF8YB	medisp
3225	Drape 2 ply PE 33 gr/m2 NW 30 gr/m2 75x75cm lateral adhesive	872059888DRAPESSF8YB	medisp
3228	Drape 2 ply 50 x 60 cm , w. Adh. Around fen.Ø 6,5 cm blue	872059888DRAPESSF8YB	medisp
3229	Drape 2 ply 60 x 50 cm w. adh. around fen. 6 x 8 cm blue	872059888DRAPESSF8YB	medisp
3230	Drape 2 ply 75 x 90 cm w. adh. around fen. 6 x 8 cm blue	872059888DRAPESSF8YB	medisp
3231	Drape 75 x 90 cm, transparent hole Ø 10 cm PE folded, with adhesive	872059888DRAPESSF8YB	medisp
3232	Drape 3 ply 70 x 50 cm, 54 g/m2 hole Ø 7 cm T/PE/NW folded	872059888DRAPESSF8YB	medisp
3233	Drape 2 ply 70 x 90 cm fen. Ø 6 cm	872059888DRAPESSF8YB	medisp
3234	Drape 3 ply 70 x 90 cm, 54 g/m2 hole Ø 10 cm T/PE/NW folded	872059888DRAPESSF8YB	medisp
3235	Drape 2 ply 75 x 90 cm fen. Ø 15 x 6 cm w. adh.	872059888DRAPESSF8YB	medisp
3236	Drape 2 ply 70 x 90 cm, 60 g/m2 hole Ø 10 cm PE/NW folded, with	872059888DRAPESSF8YB	medisp
3237	Drape 2 ply 70 x 90 cm, 60 g/m2 hole Ø 12 cm PE/NW folded, with	872059888DRAPESSF8YB	medisp
3238	Drape 3 ply 70 x 90 cm, 54 g/m2 hole Ø 10 x 12 cm T/PE/NW folded,	872059888DRAPESSF8YB	medisp
3239	Drape 3 ply 90 x 150 cm, 54 g/m2 hole Ø 10 cm T/PE/NW folded	872059888DRAPESSF8YB	medisp
3240	U-drape 2 ply 45 x 70 cm, PE/NW folded, with adhesive	872059888DRAPESSF8YB	medisp
3241	Split drape 2 ply 90 x 75 cm, PE/NW folded, with adhesive	872059888DRAPESSF8YB	medisp
3244	Drape 2 ply 75x75cm PE 35x35cm w adh around fen. Ø10cm	872059888DRAPESSF8YB	medisp
3247	Drape 2 ply 75 x 90cm adh around fen Ø 10x15cm adh corn blue	872059888DRAPESSF8YB	medisp
3248	Drape 2 ply plastic 41 x 20 cm w. fen. 7,5 x 2,5 cm	872059888DRAPESSF8YB	medisp
3256	Drape 2 ply 70 x 90 cm fen. Ø 10 cm, with split	872059888DRAPESSF8YB	medisp
3450	Drape jaw PE/NW 2 ply 100 x 100 cm split 20 x 15 cm adh blue	872059888DRAPESSF8YB	medisp
3451	Jaw drape SMS 90 x 160 cm absorbent	872059888DRAPESSF8YB	medisp
3455	Jaw drape SMS 90 x 160 cm absorbent with adhesive	872059888DRAPESSF8YB	medisp
95052	Drape jaw SMS 90x150cm with abs.field fen 10x20cm impermeabl	872059888DRAPESSF8YB	medisp
95055	Drape top reinf.. 240x150cm with 2 layer lami. adhes+velcro	872059888SURGDRAF23CS	medisp

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REF	Designation	Basic UDI-DI	Trade name
95060	Drape top 2 ply 150 x 260 cm	872059888SURGDRAPF23CS	medisp
95061	Drape top 270 x 150 cm with armboard cover	872059888SURGDRAPF23CS	medisp
95062	Drape side 100 x 112 cm with adhesive	872059888SURGDRAPF23CS	medisp
95065	Drape bottom 2 ply 180 x 196 cm	872059888SURGDRAPF23CS	medisp
95066	Drape bottom pediatric 175 x 180 cm with 80 x 2.5cm adhesive	872059888SURGDRAPF23CS	medisp
95067	Drape bottom 2 ply 180 x 196 cm with adhesive 120cm	872059888SURGDRAPF23CS	medisp
95068	Drape bottom reinf. 150x180cm, 2 layer lamin. w/ adhesi+velc	872059888SURGDRAPF23CS	medisp
95069	Drape Ophthalmic 150x105cm, with 2 fluid ,collection pouch	872059888SURGDRAPF23CS	medisp
95070	Drape sheet 100 x 150 cm	872059888SURGDRAPF23CS	medisp
95071	Drape sheet 100 x 170 cm with adhesive 100 cm	872059888SURGDRAPF23CS	medisp
95072	Drape 100 x 150 cm with adhesive	872059888SURGDRAPF23CS	medisp
95074	Drape sheet 180 x 150 cm	872059888SURGDRAPF23CS	medisp
95080	Drape sheet 150 x 250 cm, with 85 x 5 cm adhesive	872059888SURGDRAPF23CS	medisp
95085	Drape sheet 180 x 180 cm, with 85x 5 cm adhesive	872059888SURGDRAPF23CS	medisp
95220	Cover foot 16,55 x 37 cm	872059888SURGDRAPF23CS	medisp
95302	Drape lateral fenestration 2 ply 75 x 90 cm Ø 10 cm w. adh.	872059888SURGDRAPF23CS	medisp
95303	Drape lateral fenestration 2 ply 130 x 220 cm Ø10 cm w. adh.	872059888SURGDRAPF23CS	medisp
95304	Drape lateral fenestration 2 ply 130 x 250 cm Ø10 cm w. adh.	872059888SURGDRAPF23CS	medisp
95305	Drape eye SMS 40 x 40 cm incise 11,5 x 9 cm split 5 cm	872059888SURGDRAPF23CS	medisp
95307	Drape fen. 2 ply 100 x 150 cm Ø 10 x 10 cm w adhesive	872059888SURGDRAPF23CS	medisp
95312	Eye drape 40 x 40 cm, 45 g/m2 blue anti-static SMS non woven, oval	872059888SURGDRAPF23CS	medisp
95440	Drape eye 2 ply 140 x 150 cm 1 x pouch/incise hole 8 x 10 cm	872059888SURGDRAPF23CS	medisp
95442	Drape eye spunlaced 110 x 155 cm fen. 6 x 8 cm w. adh.	872059888SURGDRAPF23CS	medisp
95443	Drape eye SMS 45 gr/m2 180 x 160 cm incise/2 x pouch	872059888SURGDRAPF23CS	medisp
95444	Drape eye 2 ply 140 x 150 cm incise 1 x pouch fen. 6 x 18 cm	872059888SURGDRAPF23CS	medisp
95447	Drape eye SMS 45 gr/m2 220 x 160 cm incise/2 x pouch fen 15c	872059888SURGDRAPF23CS	medisp
95451	Drape eye-53x75cm incise and split fen. 11.5x9cm	872059888SURGDRAPF23CS	medisp
95453	Eye Drape 140x150 cm two pouches Fenestration 8x10	872059888SURGDRAPF23CS	medisp
95501	Drape angio 230 x 300 cm universal with 2 instr. panels	872059888SURGDRAPF23CS	medisp
95502	Drape angio 230 x 350 cm 4 windows Ø 9/4x6 cm	872059888SURGDRAPF23CS	medisp
95503	Drape pacemaker 228 x 330 cm 2 windows Ø 2,25 x 6 cm	872059888SURGDRAPF23CS	medisp
95504	Drape angio 220 x 330 cm instrument pannel full right side	872059888SURGDRAPF23CS	medisp
95505	Drape angio femoral 230 x 310 cm 2 windows Ø 15x17cm qw bag	872059888SURGDRAPF23CS	medisp
95506	Drape angio special XL 220x330cm 2 fen 2 part. instr. pannel	872059888SURGDRAPF23CS	medisp
95507	Drape Angio 2 ply 3 fen. 230 x 260 cm extra incision foil	872059888SURGDRAPF23CS	medisp
95510	Drape hip 300 x 200 x 350 cm flex opening and pouches	872059888SURGDRAPF23CS	medisp
95514	Drape angio 230 x 350 cm 4 windows Ø 9/4x6 cm centric 2xPE	872059888SURGDRAPF23CS	medisp
95515	Drape Pacemaker 2x incise fen. bags both on sides 230x340cm	872059888SURGDRAPF23CS	medisp
95530	Drape vertical isolation 240 x 330 cm incise 90 x 32 cm	872059888SURGDRAPF23CS	medisp
95531	Drape vertical isolation 240 x 320 cm incise 22 x 57 cm	872059888SURGDRAPF23CS	medisp
95533	Drape vert.isolation 240x320cm small incise 24x47cm no pouch	872059888SURGDRAPF23CS	medisp

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REF	Designation	Basic UDI-DI	Trade name
95540	Drape 90 x 110 cm PE transparent folded, with adhesive	872059888SURGDRAPF23CS	medisp
95560	Drape arthroscopy 230 x 310 cm with pouch	872059888SURGDRAPF23CS	medisp
95562	Drape arthroscopy 230x310cm flexible fenestr. 6cm w/pouch	872059888SURGDRAPF23CS	medisp
95565	Drape split shoulder 230 x 260 cm w. fluid control pouch	872059888SURGDRAPF23CS	medisp
95575	Drape extremity 230 x 330 cm flexible fenestration 7cm	872059888SURGDRAPF23CS	medisp
95576	Drape extremity 230 x 330 cm fenestration with T	872059888SURGDRAPF23CS	medisp
95578	Drape extremity 230 x 330 cm flexible fenestration 6cm	872059888SURGDRAPF23CS	medisp
95580	Drape hand 150/354 x 297 cm aperture size 3 cm	872059888SURGDRAPF23CS	medisp
95585	Drape hand 150/370 x 310 cm aperture 3 cm absorb. 42 x 85 cm	872059888SURGDRAPF23CS	medisp
95600	Drape craniotomy 228 x 320 cm incise/pouch	872059888SURGDRAPF23CS	medisp
95602	Drape Elekta Steriotactic PE 215 x 240 cm	872059888SURGDRAPF23CS	medisp
95606	Drape laparoscopic lithotomie pos. 260/230 x241cm Ø 26x30 cm	872059888SURGDRAPF23CS	medisp
95640	Drape TUR mesh screen 260/150 x 240 cm att. leggings	872059888SURGDRAPF23CS	medisp
95641	Drape TUR 155/255 x 162 cm w. fluid contr. pouch/finger cot	872059888SURGDRAPF23CS	medisp
95651	Drape C-section 200/250 x 286 cm w. fenestration in T-shape	872059888SURGDRAPF23CS	medisp
95652	Drape C-section 180/250 x 300 cm with incise pouch with wire	872059888SURGDRAPF23CS	medisp
95653	Drape gynaecology 260/304 cm Ø 10 x 12 cm with adhesive	872059888SURGDRAPF23CS	medisp
95654	Drape gynaecology 200/260 x 177 cm	872059888SURGDRAPF23CS	medisp
95655	Drape CV Incision 200 x 360 cm	872059888SURGDRAPF23CS	medisp
95656	Drape gynaecological fenestrated	872059888SURGDRAPF23CS	medisp
95658	Drape breast cover 250/190 x 325 cm	872059888SURGDRAPF23CS	medisp
95670	Drape thyroid 200 x 310 cm	872059888SURGDRAPF23CS	medisp
95682	Drape gynaecology 150x190x75cm w/ fen reinforced	872059888SURGDRAPF23CS	medisp
95690	Drape CV perineal 200 x 250 cm	872059888SURGDRAPF23CS	medisp
95691	Drape perineal 200 x 250 cm fen. 40 x 45 cm w. inc. foil	872059888SURGDRAPF23CS	medisp
95700	Drape PE 205 x 150 cm split 80 cm	872059888SURGDRAPF23CS	medisp
95701	Drape split PE 265 x 150 cm split 80 cm	872059888SURGDRAPF23CS	medisp
95705	Drape split large 200 x 280 cm split 23 x 76 cm	872059888SURGDRAPF23CS	medisp
95710	Drape split 270 x 230 cm split 15 x 102 cm	872059888SURGDRAPF23CS	medisp
95714	Drape Split 150x250cm, split 7x70cm	872059888SURGDRAPF23CS	medisp
95715	Drape ENT split 200 x 280 cm split 65 cm	872059888SURGDRAPF23CS	medisp
95720	Drape split 230 x 260 cm split 100X20 cm adhesive	872059888SURGDRAPF23CS	medisp
95740	Drape fenestrated ENT 220 x 230 cm hole 5 x 6 cm	872059888SURGDRAPF23CS	medisp
95745	Drape turban head 100 x 70 cm	872059888SURGDRAPF23CS	medisp
95800	Drape TUR SMS with mesh screen and condom	872059888SURGDRAPF23CS	medisp
95802	Drape pediatric 200 x 280 cm Ø 10 cm w. adhesive	872059888SURGDRAPF23CS	medisp
95805	Drape fenestrated 120 x 150 cm hole 7 x 5 cm w/adhesive	872059888SURGDRAPF23CS	medisp
95809	Drape 2 ply 112 x 150 cm, 60 g/m2 hole 10 x 15 cm PE/NW folded	872059888SURGDRAPF23CS	medisp
95812	Drape circumcise 75 x 115 cm with fenestration Ø 2 cm	872059888SURGDRAPF23CS	medisp
95835	Arm cover 2 ply 38 x 75 cm	872059888SURGDRAPF23CS	medisp
95837	Cover arm rest 20/60 x 75 cm	872059888SURGDRAPF23CS	medisp

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640075	Drape SMS 75 x 75 cm folded	872059888DRAPESSF8YB	medisp
640090	Drape SMS 90 x 90 cm blue folded	872059888DRAPESSF8YB	medisp
641050	Wrapping field SMS 40 gram 50 x 50 cm blue	872059888WRAPFIELF314X	medisp
641060	Wrapping field SMS 40 gram 60 x 60 cm blue	872059888WRAPFIELF314X	medisp
641075	Wrapping field SMS 40 gram 75 x 75 cm blue	872059888WRAPFIELF314X	medisp
641090	Wrapping field SMS 40 gram 90 x 90 cm blue	872059888WRAPFIELF314X	medisp
641100	Wrapping field SMS 40 gram 100 x 100 cm blue	872059888WRAPFIELF314X	medisp
641120	Wrapping field SMS 40 gram 120 x 120 cm blue	872059888WRAPFIELF314X	medisp
703903006	Folded field 60 x 60 cm 38 g / m ²	872059888DRAPESSF8YB	medisp
703903007	Folded field 50 x 50 cm, with hole and cut 38 g / m ²	872059888DRAPESSF8YB	medisp
95640-1	Drape TUR mesh screen 260/150 x 240 cm att. leggings	872059888SURGDRAPEF23CS	medisp

Signature:

Name: Jos van der Kwartel

Function: Management representative

Place and Date: